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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/737,446	01/10/97	DUPRE J	223/051

HM11/0331

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EXAMINER	
NOLAN,P	
ART UNIT	**PAPER NUMBER**
1644	8

DATE MAILED:
03/31/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/737,446	Dupre
Examiner	**Group Art Unit**
Nolan	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 12-29-97.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 15-37 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15-19, 23-27, 31-37 is/are rejected.

☐ Claim(s) 20-22 and 28-30 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of References Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

Part III DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.

2. Claims 15-37 are pending.

The following new grounds of rejections are necessitated by the amendment filed 12-29-97.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 31-32, 34-35 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gutniak et al.,(V).

Gutniak et al., teaches pharmaceutical compositions comprising GLP 1(7-36) amide (see page 1317-1318, in particular).

The prior art teachings anticipate the claimed invention.

Applicant's arguments filed 12-29-97 have been fully considered but are not found persuasive.

Applicant argues that the preamble in a claim carries patentable weight when it defines the claim, citing Bell Communications Research, Inc. v. Vitalink Communications Corp. 34 USPQ2d 1816 (Fed. Cir. 1995). However, as applicant has stated in summarizing the decision, the claims under discussion were method claims, not product claims, as is the case in a composition claim. In a product claim if the prior art teaches all of the components in the claim, the intended use for the product has no patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 15-19, 23-27, 33 and 36 are rejected under 35 U.S.C. § 103 as being unpatentable over Gutniak et al. (V), of record, in view of U.S. Patent 5,424,286, of record (A), D'Alessio et al., (W) newly cited.

Gutniak et al., teaches the use of GLP 1(7-36)amide in Type I diabetes, wherein GLP 1(7-36)amide decreased the need for insulin dosage required to maintain euglycemia (see abstract, in particular). Gutniak et al., also teaches that both GLP-1(7-37) and GLP-1(7-36) exerted strong insulinotropic effects in vitro and in vivo (see page 1316, in particular). Lastly Gutniak et al., teaches coadministration of insulin in type I diabetics prior to the feeding of a meal (see page, 1317).

The claimed invention differs from the prior art teachings only by the recitation of treating Type I diabetics with GLP-1(7-36)amide or GLP-1(7-37). However, in summarizing the use of the Gutniak et al., findings, the `286 patent teaches that "In patients with IDDM (i.e. Type I diabetes), the GLIP (i.e. GLP-1(7-36)amide) treatment lowered the insulin required by one half. This glucose dependent activity is a very desirable characteristic for a therapeutic agent that can be used to treat DM avoiding tile complications of hypoglycemic side effects". Lastly D'Alessio et al., also summarized to findings of Gutniak et al., by stating "It has recently been reported that infusions of GLP-1 into diabetic subjects decreased the insulin dosage required to maintain euglycemia. Furthermore, type I diabetic subjects treated with GLP-1 during one step euglycemic, hyperinsulinemic clamps had 10-15% higher rates of glucose than during control studies, thereby suggesting that GLP-1 may promote glucose uptake in addition to augmenting insulin release".

One of ordinary skill in the art at the time the invention was made would have been motivated to treat Type I diabetics with either GLP-1(7-36)amide or GLP-1(7-37) since both are known to show strong insulinotropic effects in vivo as taught by Gutniak et al. The results of the Gutniak et al., teachings, when viewed from the point of view of those skilled in the art (i.e. the '286 patent and

D'Alessio et al.) would reasonably suggest treating Type I diabetics with GLP-1(7-36)amide or GLP-1(7-37). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Applicant's arguments filed 12-29-97 have been fully considered but are not found persuasive.

Applicant argues that the `286 patent mischaracterizes the Gutniak et al., article. However, the `286 patent draws conclusions based upon experimental data taught by Gutniak et al. Furthermore, another skilled artisan, D'Alessio recognized the importance of Gutniak's et al., article when they summarized Gutniak's work in their introduction. It is well established that Type I diabetics do not produce enough insulin in response to a meal. Since Gutniak et al., teaches that GLP-1(7-36)amide decreases the need for external insulin in Type I diabetics after a meal, it would be obvious to treat Type I diabetics with the peptide.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

6. Applicant is notified that as of the current search in the prior art claims 20-22 and 28-30 are only objected to because they depend upon rejected claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-

3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196

Patrick Nolan, Ph.D.
March 27, 1998

F. Christopher Eisenschenk, Ph.D.
Primary Examiner
March 27, 1998